The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte DAVID I. GWYNNE, FRANCIS P. BUXTON,
MARK H. PICKETT, ROGER W. DAVIES, and
CLAUDIO SCAZZOCCHIO

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Appeal No. 2000-2157
Reexamination 90/005,095

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HEARD: November 28, 2000

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Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §§ 134 and 306 from the examiner's final rejection of claims 2, 3, 5, 10, 11, 13-16, and 18-20. Claims 4, 6-8, 12, 17 are also pending but have been indicated by the examiner to be allowable. Claim 19 is representative of the claims on appeal and reads as follows:

> 19. A DNA construct for use in transforming an Aspergillus host to obtain expression therein of a polypeptide, said DNA construct comprising promoter DNA for promoting transcription in Aspergillus and operably linked to DNA coding for said polypeptide to enable expression thereof in said Aspergillus host, said DNA coding for said polypeptide comprising DNA coding for a produced polypeptide, the DNA coding for the produced polypeptide being entirely foreign to said promoter DNA.

The examiner relies on the following reference:

Yelton et al. (Yelton) 4,816,405 March 28, 1989

Claims 2, 3, 5, 10, 11, 13-16, and 18-20 stand rejected under 35 U.S.C. § 102(e) over Yelton.

We reverse.

Background

As disclosed in the patent under reexamination, filamentous fungi such as those of the genus Aspergillus are useful as host cells for expression of recombinant proteins. See column 1, lines 43-54. Appellants' patent discloses that DNA constructs for expressing a foreign protein in Aspergillus host cells may include several component DNA sequences, including a promoter which is active in the fungal host cell (col. 2, lines 58-66); a coding sequence which encodes the

desired protein (col. 2, line 66 to col. 3, line 7); and a signal peptide, which directs secretion of the desired protein (col. 3, lines 8-34). The patent discloses that these DNA sequences can be combined as desired, so that the promoter/signal sequences/coding sequence combination need not be one that occurs naturally. See generally col. 2, line 55 to col. 4, line 25.

Discussion

Claim 19, the broadest claim on appeal, is drawn to a DNA construct comprising a promoter which is active in an Aspergillus host cell and DNA coding for a desired polypeptide. Claim 19 also includes the limitation that "the DNA coding for the produced polypeptide [is] entirely foreign to [the] promoter DNA." The examiner rejected this claim as being anticipated by Yelton. The examiner points to "columns 5, 7, 8 and claims 1-23" of Yelton as providing an anticipating disclosure (see Paper No. 15, page 1).

The examiner relies on Yelton's description (column 5) of how the plasmid vectors disclosed therein can be used to construct expression vectors for producing heterologous polypeptides in Aspergillus host cells. See col. 5, lines 35-46. The examiner also points to Yelton's prophetic example (columns 7-8), which describes cloning and expression of a foreign polypeptide under the control of the Aspergillus nidulans yA promoter (col. 7, line 45 to col. 8, line 41). Finally, the examiner points to the claims of Yelton, which he characterizes as "quite broad," and which must be presumed to be enabled under 35 U.S.C. § 282. As we understand it, the examiner's presumption-of-validity argument is that Yelton's claims read on cloning and expression of foreign genes under the

control of the A. nidulans trpC gene and therefore under § 282 it must be presumed that making such DNA constructs would not have required undue experimentation.

Appellants argue that Yelton would not have enabled a person of skill in the art to practice the instantly claimed invention. In support of their position, Appellants have submitted a declaration under 37 CFR § 1.132 by Joseph O. Falkinham III. The Falkinham declaration is primarily directed to the prosecution history of the Yelton patent and the claim amendments that were made in response to an enablement rejection by the examiner in that case.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Inds. Inc. v. Guardian Inds. Inc., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Thus, before we reach the issue of whether Yelton is enabling with respect to Appellants' claims, we must consider whether it identically discloses every element of the claimed invention. Again, we limit our analysis to claim 19, the broadest claim on appeal.

Claim 19 recites a DNA construct comprising an Aspergillus-operable promoter and DNA coding for a desired polypeptide. Claim 19 also requires that the "the DNA coding for the produced polypeptide [be] entirely foreign to [the] promoter DNA." The examiner cites three specific passages of Yelton to support his position that Yelton identically discloses this invention: the general guidance

found in column 5, the prophetic example found in columns 7-8, and the claims. See Paper No. 15, page 1.

The last basis—Yelton's claims—can be addressed simply by noting that a patent's claims are not a measure of its disclosure. See In re Benno, 768 F.2d 1340, 1346, 226 USPQ 683, 686 (Fed. Cir. 1985) ("The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding."). Here, Yelton's claims do not identically recite every limitation of the claimed invention and therefore do not support a rejection under § 102. [1]

The examiner also relies on column 5 of Yelton as providing an anticipatory disclosure. Column 5 contains the following description of how Yelton's vectors could be used to create Aspergillus expression vectors:

> These vectors can, in pr[i]nciple, be employed as intermediates in the construction of expression vectors for desired coding sequences operable in ascomycete hosts by sequencing the selectable marker gene fragment cloned and isolated, restricting the sequence to eliminate all or part of the coding sequence, placing the desired coding sequence under the control of the promoter and terminating sequences associated with the marker gene, and inserting this package into a cloning vector such as the intermediate here described, which contains an additional complete gene copy as a marker.

Col. 5, lines 35-46. As we understand it, the examiner views this passage as an anticipatory disclosure because it directs a skilled artisan to make an Aspergillus

[1] The examiner also relies on Yelton's claims to support his position that Yelton is enabling with respect to the instant claims. The presumption-of-validity argument, although relevant to the enablement issue, is not applicable to the issue of whether Yelton identically discloses the claimed invention.

expression vector by (1) sequencing the marker gene (i.e., trpC) fragment; (2) restricting the trpC sequence to eliminate all or part of it; (3) placing the desired coding sequence under control of the trpC promoter and terminator sequences; and (4) inserting that package into another vector, such as Yelton's pHY201, which contains an intact marker gene.

This passage is, at most, a description of how Yelton's vectors could be modified to meet all the limitations of claim 19. It is not an identical disclosure of the claimed invention, as required to support a rejection under § 102. See Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("Every element of the claimed invention must be literally present, arranged as in the claim."); Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) ("Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference.").

That Yelton spells out the required modifications does not change the fact that Yelton's disclosed invention must be modified in order to meet the limitations of the instant claims. If what is disclosed in the reference must be modified in order to meet all of the limitations of the claim, the proper basis of the rejection (if any) is 35 U.S.C. § 103.[2]

[2] The examiner has not made a rejection under 35 U.S.C. § 103, and on this record we cannot say whether such a rejection would be appropriate. For example, the examiner has pointed to no evidence showing that a person of ordinary skill in the art would have been motivated to clone a desired heterologous gene under the control of the A. nidulans trpC promoter, or to delete all of the trpC coding sequence, so as to bring the resulting DNA construct within the scope of the instant claims. Nor have we been directed to evidence that a skilled artisan would have had a reasonable expectation of success in carrying out the recited modifications. A prima facie case of obviousness would require evidence of both motivation and expectation of success. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Yelton comes closest to identically disclosing the instantly claimed construct in the prophetic example of columns 7 and 8. This example describes specifically how to clone DNA encoding a foreign protein such as "insulin or other hormones, lymphokines, growth factors, or other enzymic or structural proteins" (col. 8, lines 33-35) under the control of the promoter from the A. nidulans yA gene and how to express the cloned DNA in Aspergillus host cells.

Yelton describes the advantage of an Aspergillus expression system as follows:

> Filamentous ascomycetes are efficient and "natural" secretors of certain proteins. The secreted protions [sic] because of the structure of the organisms, are transported into the medium rather than retained in the periplasmic space. The secretion takes place through the mediation of suitable signal sequences associated with those proteins naturally secreted by the organisms.

Col. 7, lines 49-56. Yelton states that the yA gene product is a secreted enzyme (col. 7, lines 61-65). Yelton also states that, when the yA gene's promoter is used for expression of a heterologous polypeptide,

> [t]he coding sequence is placed in reading frame with the [yA] signal sequence retained in the cosmid. The new cosmid, then containing the desired heterologous coding sequence is then transformed into a filamentous ascomycete host preferably an industrial strain, and cultured to produce and secrete the desired heterologous sequence.

Col. 8, lines 35-41.

Thus, assuming arguendo that Yelton's prophetic example is enabled, the result of the described steps would be a DNA construct comprising the A. nidulans yA promoter, followed by the yA signal sequence fused in correct reading frame with DNA encoding the desired heterologous polypeptide.

Expression of this construct in an Aspergillus host cell would give a "produced polypeptide" consisting of the yA signal sequence fused to the desired polypeptide. Since the produced polypeptide resulting from Yelton's prophetic example would include the yA signal sequence, and is produced under control of the yA promoter, the exemplary construct does not meet the limitation of claim 19 that "the DNA coding for the produced polypeptide [be] entirely foreign to [the] promoter DNA." Therefore, Yelton's prophetic example does not disclose a DNA construct that meets every limitation of the instantly claimed invention, and does not anticipate the instant claims.

We find it unnecessary to reach the issue of the scope of enablement provided by Yelton's disclosure. Even assuming that Yelton is enabling for everything it discloses, the reference does not anticipate the instant claims because it does not describe every limitation of the claimed invention.

Summary

We reverse the rejection under 35 U.S.C. § 102(e) because Yelton does not describe every limitation of the instant claims.

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REVERSED

Sherman D. Winters Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

EG/dm

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